

Food and Drug Administration, HHS

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based on those reports and other available data.

(d) The additives are used or intended for use as a sweetening agent only in special dietary foods, as follows:

(1) In beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, in amounts not to exceed 12 milligrams of the additive, calculated as saccharin, per fluid ounce.

(2) As a sugar substitute for cooking or table use, in amounts not to exceed 20 milligrams of the additive, calculated as saccharin, for each expressed teaspoonful of sugar sweetening equivalency.

(3) In processed foods, in amounts not to exceed 30 milligrams of the additive, calculated as saccharin, per serving of designated size.

(e) The additives are used or intended for use only for the following technological purposes:

(1) To reduce bulk and enhance flavors in chewable vitamin tablets, chewable mineral tablets, or combinations thereof.

(2) To retain flavor and physical properties of chewing gum.

(3) To enhance flavor of flavor chips used in nonstandardized bakery products.

(f) To assure safe use of the additives, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate mixes of the additive for manufacturing purposes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive, expressed as saccharin, in any intermediate mix.

(iii) Adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraphs (d) and (e) of this section.

(2) The label of any finished food product containing the additive shall bear:

(i) The name of the additive.

(ii) The amount of the additive, calculated as saccharin, as follows:

(a) For beverages, in milligrams per fluid ounce;

(b) For cooking or table use products, in milligrams per dispensing unit;

(c) For processed foods, in terms of the weight or size of a serving which

shall be that quantity of the food containing 30 milligrams or less of the additive.

(iii) When the additive is used for calorie reduction, such other labeling as is required by part 105 or § 100.130 of this chapter.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

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181.34 Sodium nitrite and potassium nitrite.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14638, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 181 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 181.1 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the Act is exempt from classification as a food additive. The Commissioner will publish in this part all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by

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evidence to show that it falls within section 201(s)(4) of the Act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the Act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of a final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the Act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in part 189 of this chapter when appropriate.

[42 FR 14638, Mar. 15, 1977, as amended at 42 FR 52821, Sept. 30, 1977; 54 FR 39635, Sept. 27, 1989]

§ 181.5 Prior sanctions.

(a) A prior sanction shall exist only for a specific use(s) of a substance in food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958.

(b) The existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the Act but not from the other adulteration or the misbranding provisions of the Act.

(c) All known prior sanctions shall be the subject of a regulation published in this part. Any such regulation is subject to amendment to impose whatever limitation(s) or condition(s) may be necessary for the safe use of the ingre-

dient, or revocation to prohibit use of the ingredient, in order to prevent the adulteration of food in violation of section 402 of the Act.

(d) In proposing, after a general evaluation of use of an ingredient, regulations affirming the GRAS status of substances added directly to human food in part 184 of this chapter or substances in food-contact surfaces in part 186 of this chapter, or establishing a food additive regulation for substances added directly to human food in parts 172 and 173 of this chapter or food additives in food-contact surfaces in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, the Commissioner shall, if he is aware of any prior sanction for use of the ingredient under conditions different from those proposed in the regulation, concurrently propose a separate regulation covering such use of the ingredient under this part. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any food additive or GRAS regulation promulgated after a general evaluation of use of an ingredient constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to a proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this part, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

Subpart B—Specific Prior-Sanctioned Food Ingredients

§ 181.22 Certain substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the